IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Joel R. Studin	Art Unit: 1615
Serial No: 10/829,316	Examiner: Sheikh, Humera N
Filing Date: April 21, 2004	
Title: *Method and Composition for the Treatment of Scars*	Atty. Docket No.: SDF 04-14

APPEAL BRIEF

Commissioner of Patents
and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal from the Final Rejection dated August 19, 2008.

REAL PARTY IN INTEREST

The real party in interest of this application is Scarguard Labs, LLC.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF THE CLAIMS

Claims 1-16 and 30-32 have finally been rejected and are the subject of this appeal.

STATUS OF AMENDMENTS

Appellant has made no amendments since the Final Action was mailed.

SUMMARY OF CLAIMED SUBJECT MATTER

As set forth in independent claim 1, the presently claimed invention is directed to, a method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises; applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof. Support for claim 1 can be found in the specification at page 8, line 15 through page 9, line 2, page 11, lines 6-12 and in claim 1 as originally filed.

As set forth in independent claim 30, the presently claimed invention is directed to, a method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises: applying onto a healed wound a topical composition comprising collagenase. Support for claim 30 can be found in the specification at page 11, lines 6-18 and in claim 30 as originally filed.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(1) Whether the Examiner properly rejected claims 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Youssefyeh et al. (U.S. Pat. No. 5,968,519) in view of Lee (U.S. Pat. No. 5,552,162); and

(2) Whether the Examiner properly rejected claim 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Lee (U.S. Pat. No. 5,552,162).

ARGUMENT

(1) Whether the Examiner properly rejected claims 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Youssefyeh et al. (U.S. Pat. No. 5,968,519) in view of Lee (U.S. Pat. No. 5,552,162).

It is the Examiner position that, "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, such as hypertrophic scars such as taught by Lee within the methods of Youssefyeh." See Office Action dated August 19, 2008 at page 5, third paragraph. Appellant respectfully disagrees.

Claim 1

Claim 1 is directed to, "[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises: applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof." See claim 1, as presently pending (emphasis added).

As the Examiner points out, Youssefyeh et al. is directed to the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, urticaria, psoriasis, erythema), gingivitis and acute injury. The Examiner further points out that Youssefyeh et al. teaches the use of topical formulations containing corticosteroids and a film-forming material, such as cellulose derivatives. However, Appellant respectfully points out that Youssefyeh et al. does not disclose or suggest a method for treating healed wounds so as to reduce scarring and/or improve the appearance of scars. In fact, the Examiner acknowledges this, stating that Youssefyeh "does not explicitly teach treatment of 'healed wounds.'" See Office Action dated August 19, 2008 at page 4, third paragraph.

Nevertheless, according to the Examiner, "the methods of treatment and conditions to be treated as taught by Youssefyeh would include application upon healed wounds so as to reduce scarring and/or improve the appearance thereof." See Office Action dated August 19, 2008 at page 4, third paragraph. The Examiner further states, "scarring, such as keloid formation, can occur as a result of inflammation, either mild or intense." See Office Action dated August 19, 2008 at page 8. Appellant strenuously disagrees with this reasoning.

Again, Appellant respectfully points out that Youssefyeh et al. does not teach or suggest treating healed wounds to reduce scarring and/or improve the appearance of scars. Moreover, there is simply no indication whatsoever that the compositions disclosed in Youssefyeh et al. can be used for "treating healed wounds so as to reduce scarring and/or improve the appearance of scars," as presently claimed.

Furthermore, Appellant respectfully asserts that the treatment of inflammation and pain associated with inflammatory dermatoses, gingivitis and acute injury, as taught and disclosed in Youssefyeh et al., is not the same as treating healed wounds so

as to reduce scarring and/or improve the appearance of scars, as presently claimed. Moreover, the methods taught by the present invention and those taught by Youssefyeh et al., are directed to treating completely different conditions. Again, the former discloses a method to reduce scarring and/or improve the appearance of scars and the later teaches a method of treatment for inflammation and pain associated with inflammatory dermatoses. Inflammatory dermatoses is an inflammation of the skin, an immune response or reaction usually due to an external stimulus such as a sun burn, poison ivy, infection, etc. In contrast, scarring is a natural part of the body's healing process. A scar results from the biologic process of wound repair in the skin when the dermis layer is damaged. As part of the wound healing process, the body forms new collagen fibers to mend the damage. Occasionally, typically when the wound is particularly bad or deep, an overgrowth of collagen can occur, thereby resulting in scar formation. In most cases, scars typically form after a wound is completely healed. As such, Appellant respectfully points out that, scarring is not a form of inflammatory dermatoses, and likewise, inflammatory dermatoses is not a form of scarring. Rather, they are completely separate conditions with different causes, and more importantly, require different means of treatment.

Again, as previously pointed out, the presently claimed invention is directed to, "[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises: applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof." See claim 1, as presently pending (emphasis added). This method is not remotely taught or suggested by Youssefyeh et al. Furthermore, Youssefyeh et al. does not teach or suggest a method of treating a healed

wound. Again, contrary to the Examiner's contention, Appellant respectfully asserts that the disclosure of a method to treat an inflammatory dermal condition does not in any way suggest treating **healed wounds** to reduce scarring or improve the appearance of scars. Moreover, there is simply no suggestion whatsoever, that the compositions disclosed in Youssefyeh et al. can be used for "treating healed wounds so as to reduce scarring and/or improve the appearance of scars," as presently claimed.

The Examiner cites Lee to overcome the deficiencies of Youssefyeh et al. As the Examiner points out, Lee is directed to a method for improving the size and appearance of scar tissue. According to Lee, the method for improving scarring comprises stimulating collagenase activity in the scar by applying a thermal insulating material that elevates the surface temperature of the scar. See Lee in the Abstract. Lee also discloses the use of a therapeutically effective medicament with the thermal insulating material. Again, see Lee in the Abstract. However, Lee does not teach or suggest the use of a fluid, film-forming carrier and hardening that carrier into a tangible membrane juxtaposed to the healed wound to reduce scarring or improve the appearance of scars, as presently claimed.

Nevertheless, according to the Examiner, "Lee clearly resolves the deficiencies of Youssefyeh primary reference in their teaching of a method for improving the size and appearance of scar tissue associated with keloids or hypertrophic wound healing disorders." See Office Action dated August 19, 2008 at page 8, first paragraph. The Examiner continues, "Lee amply describes and teaches such a method of treating scars whereby a hydrogel is applied to cover the scar and teaches the same elements, used for the same purpose as that desired by Applicant. Thus, the references, in combination, address the same method of treatment using the

same process steps employed by Applicant." See Office Action dated August 19, 2008 at page 8, first paragraph. Appellant respectfully disagrees.

Again, although Lee teaches a method for improving the size and appearance of a scar, Lee does not teach or suggest the use of a film-forming carrier to treat a healed wound to reduce scarring or improve the appearance of scars, as presently claimed. Moreover, Appellant respectfully asserts that one of skill in the art would not look to the composition disclosed in Youssefyeh et al. to treat scar tissue. Again, there is simply no indication whatsoever in Youssefyeh et al. that the composition disclosed therein can be used to treat healed wounds to reduce scarring or improve the appearance of scars. Again, scarring is not a form of inflammatory dermatoses, and likewise, inflammatory dermatoses is not a form of scarring. As such, Appellant respectfully asserts that one of skill in the art would not look to Youssefyeh et al. to improve the formulation disclosed in Lee for treating scars. There is simply no reason to combine elements of the composition disclosed in Youssefyeh et al., which teaches a composition for treatment of inflammation and pain, with elements of the composition disclosed in Lee, which teaches a composition for treating scar tissue. Appellant respectfully points out that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some reason to do so.

Moreover, it is Appellant's position that one of skill in the art, without the benefit of Appellant's disclosure, would not be capable of arriving at the presently claimed invention. Appellant respectfully asserts that the Examiner is relying on Appellant's claim and/or disclosure to piece together elements to provide an argument for obviousness. Such piece-mealing together of elements in not permitted. Moreover, without looking to Appellant's specification there is simply no reason to

combine the specific elements claimed (a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound and using that composition to treat healed wounds to reduce scarring or improve the appearance of scars), from among the disclosures of Youssefyeh et al. and Lee to come up with the presently claimed film. There is simply no suggestion whatsoever of the presently claimed combination in Youssefyeh et al. or Lee.

As such, Appellant respectfully asserts that prior to Appellant's invention the use of a film-forming carrier to treat a healed wound to reduce scarring or improve the appearance of scars was not known. Furthermore, Appellant respectfully asserts that the combination of Youssefyeh et al. with Lee does not and cannot render obvious the presently claimed invention. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim 30

Claim 30 is directed to, "[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprising: applying onto a healed wound a topical composition comprising collagenase." See claim 30, as presently pending (emphasis added).

As previously pointed out, Youssefyeh et al. does not teach or suggest a method of treating healed wounds to reduce scarring and/or improve the appearance of scars, as presently claimed. Again, as pointed out hereinabove, scarring is not a form of inflammatory dermatoses, and likewise, inflammatory dermatoses is not a form of scarring. Furthermore, Youssefyeh et al. does not teach or suggest the use of

a composition comprising collagenase to treat and/or improve scarring. In fact, there is no mention whatsoever in Youssefyeh et al. of collagenase.

As previously pointed out, Lee is directed to a method for improving scarring comprises stimulating collagenase activity in the scar by applying a thermal insulating material that elevates the surface temperature of the scar. See Lee in the Abstract. However, there is no mention or suggestion whatsoever in Lee of including collagenase in a composition for treating and/or reducing scarring, as presently claimed.

As such, Appellant respectfully asserts that the combination of Youssefyeh et al. with Lee does not teach or suggest all the claim limitations of claim 30, and thus, the combination cannot and does not render obvious claim 30. It is well settled that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. Likewise, claims 31-32, which depend from claim 30 are not rendered obvious. Reconsideration and withdrawal of this rejection are respectfully requested.

(2) Whether the Examiner properly rejected claim 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Lee (U.S. Pat. No. 5,552,162).

According to the Examiner, "Mantelle ('070) teaches flexible, finite, bioadhesives compositions and methods for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents." See Office Action dated August 19, 2008 at page 5, last paragraph. The Examiner continues, "[w]hile the prior art does not explicitly teach treatment of 'healed wounds', the prior art nonetheless explicitly teaches compositions that are topically applied on the skin for

the effective treatment of pain. The method comprises applying a therapeutically effective amount of a pharmaceutical agent, a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent in the carrier. The compositions are suitable for topical application on the skin." See Office Action dated August 19, 2008 at page 6, fifth paragraph.

According to the Examiner, Lee teaches a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound healing disorder that comprises stimulating collagenase activity in the scar. The method comprises covering the scar with a hydrogel or thermally insulated material that elevates the surface temperature of the scar and that can contain a therapeutically effective amount of medicament." See Office Action dated August 19, 2008 at page 6, last paragraph. The Examiner then concludes, "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, particularly hypertrophic scars such as taught by Lee within the methods of Mantelle." See Office Action dated August 19, 2008 at page 7, second paragraph. Appellant respectfully disagrees with this conclusion.

As previously mentioned, the presently claimed invention is directed to, "[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises: applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof." See claim 1, as presently pending (emphasis added). This method is not taught or suggested by Mantelle. Rather, as the Examiner points out, Mantelle is directed to a flexible, finite, bioadhesives compositions and methods for topical application comprising a therapeutically effective amount of a

pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents. Appellant respectfully points out that Mantelle does not teach or suggest a method to treat healed wounds to reduce scarring or improve the appearance of scars. In fact, there is no mention or suggestion whatsoever in Mantelle that the composition disclosed therein can be used for treating a healed wound so as to reduce and/or improve the appearance of scarring. Examiner has acknowledged this, stating, "Mantelle does not teach treating a hypertrophic scar." See Office Action dated August 19, 2008 at page 6, second to last paragraph.

The Examiner cites Lee to overcome the deficiencies of Mantelle. As the Examiner points out, Lee is directed to a method for improving the size and appearance of scar tissue. According to Lee, the method for improving scarring comprises stimulating collagenase activity in the scar by applying a thermal insulating material that elevates the surface temperature of the scar. See Lee in the Abstract. Lee also discloses the use of a therapeutically effective medicament with the thermal insulating material. Again, see Lee in the Abstract. However, Lee does not teach or suggest the use of a fluid, film-forming carrier and hardening that carrier into a tangible membrane juxtaposed to the healed wound in method for treating healed wounds to reduce scarring or improve the appearance of scars, as presently claimed. Moreover, Appellant respectfully asserts that prior to Appellant's invention the use of a film-forming carrier to treat a healed wound to reduce scarring or improve the appearance of scars was not known.

Furthermore, Appellant respectfully asserts that one of skill in the art would not look to the compositions disclosed in Mantelle to treat scar tissue. Again, there is simply no indication whatsoever in Mantelle that the composition disclosed therein can be used to treat healed wounds to reduce scarring or improve the appearance of

scars. Furthermore, Appellant respectfully asserts that one of skill in the art would not look to Mantelle to improve the formulation disclosed in Lee for treating scars. There is simply no reason to combine elements of the composition disclosed in Mantelle with elements of the composition disclosed in Lee, which teaches a composition for treating scar tissue. Appellant respectfully points out that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some reason to do so.

Moreover, it is Appellant's position that one of skill in the art, without the benefit of Appellant's disclosure, would not be capable of arriving at the presently claimed invention. Appellant respectfully asserts that the Examiner is relying on Appellant's claim and/or disclosure to piece together elements to provide an argument for obviousness. Such piece-mealing together of elements in not permitted. Moreover, without looking to Appellant's specification there is simply no reason to combine the specific elements claimed (a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound and using that composition to treat healed wounds to reduce scarring or improve the appearance of scars), from among the disclosures of Mantelle and Lee to come up with the presently claimed film. There is simply no suggestion whatsoever of the presently claimed combination in Mantelle or Lee.

As such, Appellant respectfully asserts that the combination of Mantelle with Lee does not and cannot render obvious the presently claimed invention. Reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSIONS

Appellant respectfully asserts that the combination of Youssefyeh et al. with Lee does not and cannot render obvious the presently claimed invention. The combination does not teach or suggest a method for treating healed wounds so as to reduce scarring and/or improve the appearance of scars. Furthermore, Appellant respectfully asserts that there is simply no reason to combine elements of the composition disclosed in Youssefyeh et al., which teaches a composition for treatment of inflammation and pain, with elements of the composition disclosed in Lee, which teaches a composition for treating scar tissue. With regards to claims 30-32, Appellant respectfully points out that the combination of Youssefyeh et al. and Lee does not teach or suggest the use of collagenase in a composition for treating and/or improving the appearance of scaring.

Furthermore, Appellant respectfully asserts that the combination of Mantelle with Lee does not and cannot render obvious the presently claimed invention. The combination does not teach or suggest a method for treating healed wounds so as to reduce scarring and/or improve the appearance of scars. Furthermore, Appellant respectfully asserts that there is simply no reason to combine elements of the composition disclosed in Mantelle with elements of the composition disclosed in Lee.

Respectfully submitted,

December 22, 2008
Date

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CLAIMS APPENDIX

The pending claims in this application are:

1. (Previously Amended) A method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises; applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof.

2. (Original) The method of claim 1, wherein the film-forming carrier comprises Collodion or Flexible Collodion.

3. (Original) The method of claim 1, wherein said composition is applied onto the healed wound by brushing, rolling, extruding or applying drops of said composition.

4. (Original) The method of claim 3, wherein said composition is applied to the healed wound by brushing.

5. (Original) The method of claim 1, wherein said composition includes an active ingredient capable of reducing scarring or improving the appearance of scars selected from a topical steroid, silicone-gel, vitamin and mixtures thereof.

6. (Original) The method of claim 5, wherein said active ingredient includes a corticosteroid or a pharmaceutically acceptable salt thereof.

7. (Original) The method of claim 5, wherein said active ingredient

comprises a combination of a topical steroid and silicone-gel.

8. (Original) The method of claim 5, wherein said active ingredient is a silicone-gel.

9. (Original) The method of claim 7, wherein said composition further includes vitamin E.

10. (Original) The method of claim 1, wherein said film-forming carrier is a cellulosic derivative.

11. (Original) The method of claim 10, wherein said cellulosic derivative is nitrocellulose.

12. (Original) The method of claim 10, wherein said cellulosic derivative is methyl cellulose.

13. (Original) The method of claim 1, wherein said film-forming carrier comprises a silicone resin.

14. (Original) The method of claim 1, wherein said healed wound comprises a hypertrophic scar.

15. (Original) The method of claim 1, wherein said healed wound is one formed after surgery.

16. (Original) The method of claim 1, wherein said healed wound is formed after accidental trauma.

17.-29. (Previously Cancelled)

30. (Previously Amended) A method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises: applying onto a healed wound a topical composition comprising collagenase.

31. (Original) The method of claim 30, wherein said topical composition comprises collagenase contained within a fluid, film-forming carrier, subsequent to applying said composition onto said healed wound, hardening said carrier into a tangible membrane juxtaposed to the healed wound.

32. (Original) The method of claim 30, wherein said topical composition comprises collagenase contained within a topical creme, ointment, lotion or gel.

33.-54. (Previously Cancelled)

EVIDENCE APPENDIX

Not Applicable

RELATED PROCEEDINGS APPENDIX

Not Applicable